

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MISSOURI  
WESTERN DIVISION**

**SARAH HOOVER,**

**Plaintiff,**

**v.**

**BAYER HEALTHCARE  
PHARMACEUTICALS INC.,**

**Defendant.**

**CASE No. 3:14-cv-05090-SRB**

**BAYER HEALTHCARE PHARMACEUTICAL INC.'S ORIGINAL ANSWER**

Defendant Bayer HealthCare Pharmaceuticals Inc. ("BHCP"), by and through its undersigned counsel, hereby answers Plaintiff's Complaint (the "Complaint"). BHCP specifically denies each and every allegation of the Complaint not otherwise expressly admitted, qualified, or denied in this Answer.

**FIRST RESPONSE TO "PARTIES"**

1. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint

2. BHCP admits that it is a Delaware corporation with its principal place of business located at 100 Bayer Boulevard, Whippany, New Jersey 07981.

3. BHCP admits that Bayer HealthCare Pharmaceuticals Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

4. The allegations contained in Paragraph 4 are denied as stated. BHCP admits that Bayer HealthCare Pharmaceuticals Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

5. BHCP admits that it is the holder of the approved “NDA” for the contraceptive system Mirena®.

6. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, advertised, promoted, marketed, sold, and distributed Mirena® as an intrauterine contraceptive system (“IUS”). Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 6, BHCP is without knowledge or information sufficient to form a belief as to the truth of those.

7. BHCP admits that, at certain times not specifically set forth in the Complaint, it sold Mirena® in the United States, including Missouri. BHCP denies the remaining allegations in Paragraph 7.

8. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, marketed, distributed, and/or sold Mirena® in the United States. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 8, BHCP is without knowledge or information sufficient to form a belief as to the truth of those. BHCP denies the remaining allegations in Paragraph 8.

#### **FIRST RESPONSE TO “JURISDICTION AND VENUE”**

9. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint.

10. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

### **FIRST RESPONSE TO “FACTS”**

12. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 11 of the Complaint.

13. BHCP admits that Mirena<sup>®</sup> is an IUS made of soft, flexible plastic, which is put in place by a healthcare provider during an office visit. BHCP also admits that Mirena<sup>®</sup> contains 52 mg of levonorgestrel, which is released at a rate of approximately 20 mcg/day. This rate decreases progressively to half that value after 5 years.

14. BHCP admits that the FDA approved Berlex Laboratories, Inc.’s new drug application in December 2000.

15. BHCP admits that in 2009 the FDA approved Mirena<sup>®</sup> as a treatment indicated for heavy menstrual bleeding.

16. BHCP admits that Mirena<sup>®</sup> has been chosen by over 15 million women worldwide, 2 million in the United States. BHCP denies any remaining allegations in Paragraph 16 of the Complaint.

17. BHCP admits that Mirena<sup>®</sup> is a levonorgestrel-releasing intrauterine contraceptive that delivers small amounts of hormone directly to the uterus.

18. BHCP answers that, to the extent Paragraph 18 of the Complaint purports to quote from the FDA-approved Patient Information Booklet, that document speaks for itself. To the extent that Plaintiff’s allegations are inconsistent with the actual language and content of the document, BHCP denies those allegations.

19. BHCP admits that the allegations in Paragraph 19 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for

itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

20. BHCP admits that the allegations in Paragraph 20 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

21. BHCP admits that the allegations in Paragraph 21 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

22. BHCP admits that the allegations in Paragraph 22 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

23. BHCP admits that the allegations in Paragraph 23 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

24. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint.

25. BHCP admits that the allegations in Paragraph 25 purport to summarize or interpret from the FDA-approved Physician Prescribing Information, which document, being in

writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

26. Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations of Paragraph 26 as written. To the extent the allegations in Paragraph 26 purport to summarize from the FDA-approved Physician Prescribing Information, that document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

27. Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 27 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

28. BHCP admits that Mirena<sup>®</sup> includes an FDA-approved Patient Information Booklet.

29. Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 29 purport to summarize from the FDA-approved Patient Information Booklet, that document speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language and content of the document, BHCP denies those allegations.

30. Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

31. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of the Complaint.

32. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 of the Complaint.

33. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 of the Complaint.

34. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint.

35. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint.

36. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint.

37. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of the Complaint.

38. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 of the Complaint.

39. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 of the Complaint.

40. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of the Complaint.

41. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint.

42. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint.

43. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of the Complaint. Therefore, BHCP denies these allegations.

44. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of the Complaint.

45. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint.

46. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of the Complaint.

47. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint.

48. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint.

49. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 of the Complaint.

50. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 50 of the Complaint.

51. To the extent the allegations in Paragraph 51 apply to Mirena<sup>®</sup>, BCHP denies. To the extent the allegations in Paragraph 51 apply to a product other than Mirena<sup>®</sup>, BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of the Complaint.

52. To the extent the allegations in Paragraph 52 apply to Mirena<sup>®</sup>, BHP denies. To the extent the allegations in Paragraph 52 apply to a product other than Mirena<sup>®</sup>, BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint.

53. BHP denies the allegations in Paragraph 53 of the Complaint.

54. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 of the Complaint.

55. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 55 of the Complaint.

56. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint.

57. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of the Complaint.

58. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 58 of the Complaint.

59. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 59 of the Complaint.

60. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 60 of the Complaint.

61. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 61 of the Complaint.

62. BHP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 of the Complaint.



63. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63 of the Complaint.

64. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64 of the Complaint.

65. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 65 of the Complaint.

66. Paragraph 66 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations of Paragraph 66 as written. To the extent the allegations in Paragraph 66 purport to summarize from the FDA-approved Physician Prescribing Information, that document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

67. Paragraph 67 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 67 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

68. BHCP denies the allegations in Paragraph 68 of the Complaint.

69. The allegations contained in Paragraph 69 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the remaining allegations in Paragraph 69 purport to summarize from the DDMAC letter, which document, being in writing, speaks for itself. To the extent

Plaintiff's allegations are inconsistent with the actual language or content of the referenced document, BHCP denies those allegations.

70. The allegations contained in Paragraph 70 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 70 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations.

71. The allegations contained in Paragraph 71 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 71 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations.

72. The allegations contained in Paragraph 72 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 72 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations.

73. The allegations contained in Paragraph 73 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 73 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speaks for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations. Further, BHCP denies making any false representations with regard to Mirena<sup>®</sup>.

74. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74 of the Complaint.

75. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 75 of the Complaint.

76. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 of the Complaint.

77. Paragraph 77 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

78. Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP is without knowledge or information sufficient to form a belief as to the truth of whether Plaintiff "received" and "read" BHCP's "patient Information Booklet." BHCP denies any remaining allegations in Paragraph 78 of the Complaint.

79. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 79 of the Complaint.

80. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 80 of the Complaint.

81. Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

82. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 82 of the Complaint.

83. Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

84. Paragraph 84 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

**FIRST RESPONSE TO “COUNT I NEGLIGENCE”**

85. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 84 of the Complaint.

86. BHCP admits that, at certain times not specifically set forth in the Complaint, it sold Mirena<sup>®</sup> in the United States, including Missouri. BHCP denies the remaining allegations in Paragraph 86.

87. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 87, BHCP is without knowledge or information sufficient to form a belief as to the truth of those.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

89. Paragraph 89 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

90. Paragraph 90 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

91. Paragraph 91 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

92. Paragraph 92 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

93. Paragraph 93 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

94. Paragraph 94 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

95. Paragraph 95 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

96. Paragraph 96 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

97. Paragraph 97 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

98. Paragraph 98 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

99. Paragraph 99 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

100. Paragraph 100 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, BHCP denies.

101. Paragraph 101 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

102. Paragraph 102 (and its subparts) contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

103. Paragraph 103 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

104. Paragraph 104 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

105. Paragraph 105 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

106. Paragraph 106 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

107. Paragraph 107 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 107 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations. BHCP denies any additional allegations in Paragraph 107.

108. Paragraph 108 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

109. Paragraph 109 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

110. Paragraph 110 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

111. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 111.

**FIRST RESPONSE TO “COUNT II DESIGN DEFECT”**

112. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 111 of the Complaint.

113. BHCP admits that, at certain times not specifically set forth in the Complaint, it sold Mirena<sup>®</sup> in the United States, including Missouri. BHCP denies the remaining allegations in Paragraph 113.

114. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 114, BHCP is without knowledge or information sufficient to form a belief as to the truth of those.

115. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 115, BHCP is without knowledge or information sufficient to form a belief as to the truth of those.

116. Paragraph 116 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

117. Paragraph 117 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

118. Paragraph 118 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

119. Paragraph 119 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

120. Paragraph 120 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

121. Paragraph 121 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

122. Paragraph 122 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

123. Paragraph 123 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

124. Paragraph 124 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

125. Paragraph 125 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

126. Paragraph 126 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

127. Paragraph 127 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

128. Paragraph 128 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

129. Paragraph 129 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

130. Paragraph 130 contains legal conclusions to which no response is required. To



the extent a response is deemed necessary, BHCP denies.

131. Paragraph 131 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

132. Paragraph 132 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

133. Paragraph 133 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

134. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 134.

**FIRST RESPONSE TO “COUNT III FAILURE TO WARN”**

135. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 134 of the Complaint.

136. Paragraph 136 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

137. Paragraph 137 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

138. Paragraph 138 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

139. Paragraph 139 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

140. Paragraph 140 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

141. Paragraph 141 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

142. Paragraph 142 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

143. Paragraph 143 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

144. Paragraph 144 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

145. Paragraph 145 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

146. Paragraph 146 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

147. Paragraph 147 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

148. Paragraph 148 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

149. Paragraph 149 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

150. Paragraph 150 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

151. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151 of the Complaint. To the extent a response is deemed necessary, BHCP denies.

152. Paragraph 152 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

153. Paragraph 153 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

154. Paragraph 154 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegation that “Plaintiff did not have the same knowledge as Defendant.”

155. Paragraph 155 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

156. Paragraph 156 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

157. Paragraph 157 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

158. Paragraph 158 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

159. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 159.

**FIRST RESPONSE TO “COUNT IV STRICT LIABILITY”**

160. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 159 of the Complaint.

161. Paragraph 161 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

162. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, marketed, distributed, and/or sold Mirena<sup>®</sup>. Due to the vagueness, ambiguity and potential redundancy of any remaining allegations in Paragraph 162, BHCP is

without knowledge or information sufficient to form a belief as to the truth of those.

163. Paragraph 163 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

164. Paragraph 164 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

165. Paragraph 165 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

166. Paragraph 166 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

167. Paragraph 167 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

168. Paragraph 168 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

169. Paragraph 169 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

170. Paragraph 170 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

171. Paragraph 171 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

172. Paragraph 172 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

173. Paragraph 173 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

174. Paragraph 174 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

175. Paragraph 175 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

176. Paragraph 176 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

177. Paragraph 177 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

178. Paragraph 178 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

179. Paragraph 179 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

180. Paragraph 180 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

181. Paragraph 181 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

182. Paragraph 182 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

183. Paragraph 183 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

184. Paragraph 184 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

185. Paragraph 185 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, BHCP denies.

186. Paragraph 186 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

187. Paragraph 187 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

188. Paragraph 188 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

189. Paragraph 189 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

190. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 190.

**FIRST RESPONSE TO “COUNT V BREACH OF IMPLIED WARRANTY”**

191. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 190 of the Complaint.

192. Paragraph 192 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

193. Paragraph 193 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

194. Paragraph 194 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

195. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 195 of the Complaint.

196. Paragraph 196 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

197. Paragraph 197 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

198. Paragraph 198 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

199. Paragraph 199 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

200. Paragraph 200 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

201. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 201.

**FIRST RESPONSE TO “COUNT VI BREACH OF EXPRESS WARRANTY”**

202. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 201 of the Complaint.

203. Paragraph 203 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

204. Paragraph 204 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

205. Paragraph 205 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

206. Paragraph 206 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

207. Paragraph 207 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

208. Paragraph 208 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

209. Paragraph 209 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

210. Paragraph 210 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

211. Paragraph 211 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

212. Paragraph 212 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

213. BHCP denies Plaintiff is entitled to the relief sought Paragraph 213.

**FIRST RESPONSE TO “COUNT VII NEGLIGENT MISREPRESENTATION”**

214. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 213 of the Complaint.

215. Paragraph 215 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

216. Paragraph 216 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

217. Paragraph 217 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

218. Paragraph 218 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.



219. Paragraph 219 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

220. Paragraph 220 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

221. Paragraph 221 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

222. Paragraph 222 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

223. Paragraph 223 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

224. Paragraph 224 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

225. BHCP denies Plaintiff is entitled to the relief sought Paragraph 225.

**FIRST RESPONSE TO “COUNT VIII FRAUDULENT MISREPRESENTATION”**

226. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 225 of the Complaint.

227. Paragraph 227 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

228. Paragraph 228 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

229. Paragraph 229 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

230. Paragraph 230 of the Complaint contains legal conclusions to which no response

is required. To the extent a response is deemed necessary, BHCP denies.

231. Paragraph 231 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

232. Paragraph 232 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

233. Paragraph 233 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

234. Paragraph 234 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

235. Paragraph 235 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

236. Paragraph 236 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

237. Paragraph 237 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

238. Paragraph 238 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

239. Paragraph 239 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

240. Paragraph 240 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

241. Paragraph 241 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

242. Paragraph 242 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

243. BHCP denies Plaintiff is entitled to the relief sought Paragraph 243.

**FIRST RESPONSE TO “COUNT IX  
FRAUD BY SUPPRESSION AND CONCEALMENT”**

244. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 243 of the Complaint.

245. Paragraph 245 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

246. Paragraph 246 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

247. Paragraph 247 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

248. Paragraph 248 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

249. Paragraph 249 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

250. Paragraph 250 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

251. Paragraph 251 of the Complaint contains legal conclusions to which no response

is required. To the extent a response is deemed necessary, BHCP denies.

252. Paragraph 252 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

253. Paragraph 253 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

254. Paragraph 254 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

255. Paragraph 255 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

256. Paragraph 256 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

257. Paragraph 257 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

258. Paragraph 258 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

259. BHCP denies Plaintiff is entitled to the relief sought Paragraph 259.

**FIRST RESPONSE TO “REQUEST FOR PUNITIVE DAMAGES”**

260. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 259 of the Complaint.

261. Paragraph 261 (and its subparts) of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

262. Paragraph 262 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

263. Paragraph 263 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

264. Paragraph 264 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

265. Paragraph 265 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies.

266. BHCP denies Plaintiff is entitled to the relief sought Paragraph 266. BHCP also denies Plaintiff is entitled to the relief sought in the unnumbered “Wherefore” paragraph (and its subparts) immediately following Paragraph 266.

#### **AFFIRMATIVE/SEPARATE DEFENSES**

267. Discovery and investigation may reveal that one or more of the following additional defenses should be available to defendant. Bayer HealthCare Pharmaceuticals Inc. accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer HealthCare Pharmaceuticals Inc. may withdraw any of these additional defenses as may be appropriate. Bayer HealthCare Pharmaceuticals Inc. further reserves the right to amend its Answer and defenses to assert additional defenses and other claims, as discovery proceeds. Further answering, and by way of additional defense, Bayer HealthCare Pharmaceuticals Inc. states as follows:

#### **FIRST SEPARATE DEFENSE TO ALL COUNTS**

268. Plaintiff’s Complaint and each and every count contained therein fails to state a cause of action or claim on which relief can be granted.

#### **SECOND SEPARATE DEFENSE TO ALL COUNTS**

269. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose, pursuant to RSMo. §516.190.

**THIRD SEPARATE DEFENSE TO ALL COUNTS**

270. Plaintiff's claims are barred in whole or in part by laches, waiver, and/or estoppel.

**FOURTH SEPARATE DEFENSE TO ALL COUNTS**

271. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

**FIFTH SEPARATE DEFENSE TO ALL COUNTS**

272. To the extent applicable to the facts and circumstances of this case, Plaintiff is not a real party in interest and lack capacity and/or standing to bring the claims asserted in the Complaint.

**SIXTH SEPARATE DEFENSE TO ALL COUNTS**

273. If Plaintiff suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiff. Plaintiff's recovery accordingly is barred or should be reduced by Plaintiff's assumption of the risk.

**SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

274. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, deceit, concealment, suppression and/or omission, and fails to allege the circumstances constituting fraud with the required particularity.

**EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

275. The alleged damages and injuries, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including BHCP.

**NINTH SEPARATE DEFENSE TO ALL COUNTS**

276. Plaintiff did not suffer any actual injury, loss, or damages because of the alleged use of Mirena<sup>®</sup>.

**TENTH SEPARATE DEFENSE TO ALL COUNTS**

277. The injuries and damages sustained by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and no act or omission on the part of BHCP was a proximate or competent producing cause of such alleged injuries or damages.

**ELEVENTH SEPARATE DEFENSE TO ALL COUNTS**

278. The injuries and damages sustained by Plaintiff, if any, were caused, in whole or in part, by pre-existing or subsequent physical, medical, and/or physiological conditions, for which BHCP has no legal responsibility.

**TWELFTH SEPARATE DEFENSE TO ALL COUNTS**

279. The acts and omissions of Plaintiff and/or other persons or entities, over whom BHCP had no supervision or control and for whose actions and omissions BHCP has no legal responsibility, caused or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrine of comparative negligence. Plaintiff's recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with applicable law.

**THIRTEENTH SEPARATE DEFENSE TO ALL COUNTS**

280. Plaintiff's claims are barred pursuant to the Restatement (Second) of Torts, section 402A, comment k.

#### **FOURTEENTH SEPARATE DEFENSE TO ALL COUNTS**

281. To the extent applicable to Plaintiff's claims, BHCP will rely upon the rights, defenses and presumptions accorded to it under the terms and provisions of RSMo § 537.760, et seq.

#### **FIFTEENTH SEPARATE DEFENSE TO ALL COUNTS**

282. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under Missouri law, including but not limited to RSMo 490.715, or any other applicable law.

#### **SIXTEENTH SEPARATE DEFENSE TO ALL COUNTS**

283. Plaintiff's claims are barred because Mirena<sup>®</sup> was neither defective nor unreasonably dangerous in its design, manufacture, or marketing, was reasonably safe and reasonably fit for its intended use, and was properly prepared in accordance with the applicable standard of care. The warnings and instructions accompanying Mirena<sup>®</sup> at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

#### **SEVENTEENTH SEPARATE DEFENSE TO ALL COUNTS**

284. To the extent applicable under governing law, Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine.

#### **EIGHTEENTH SEPARATE DEFENSE TO ALL COUNTS**

285. BHCP did not sell or distribute Mirena<sup>®</sup> to Plaintiff, and Plaintiff did not receive or rely on any representations or warranties as alleged in the Complaint. Plaintiff's claims for



breach of warranty are barred by lack of privity between Plaintiff on one hand and BHCP on the other.

**NINETEENTH SEPARATE DEFENSE TO ALL COUNTS**

286. Plaintiff did not detrimentally rely on any labeling, warnings, or information concerning Mirena<sup>®</sup>.

**TWENTIETH SEPARATE DEFENSE TO ALL COUNTS**

287. Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give timely notice of any alleged breach of warranty.

**TWENTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

288. Plaintiff's claims of breach of warranty are barred by the applicable provisions of Missouri law or other applicable law.

**TWENTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

289. Plaintiff's Complaint fails to state a claim upon which relief can be granted against BHCP in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription contraceptive system Mirena<sup>®</sup>, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the product was designed, manufactured, marketed and sold in a reasonable and prudent manner based upon available medical and scientific knowledge.

**TWENTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

290. Mirena<sup>®</sup> complied with the applicable product safety regulations promulgated by the United States Food and Drug Administration. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing,

distribution, marketing, and sale of Mirena<sup>®</sup>, and that it was neither defective nor unreasonably dangerous.

**TWENTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

291. If Plaintiff sustained the injuries or incurred the expenses as alleged in the Complaint, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of Mirena<sup>®</sup>. Plaintiff's recovery accordingly is barred.

**TWENTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

292. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal government's regulation of the manufacturing, testing, marketing, sale and labeling of prescription drugs.

**TWENTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

293. Plaintiff's claims regarding warnings and labeling are barred by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration is charged under law with determining the content of warnings and labeling for prescription drugs.

**TWENTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

294. Plaintiff cannot state a claim with regard to the warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the United States Food and Drug Administration.

**TWENTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

295. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the United States Food and Drug Administration.

#### **TWENTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

296. Any claims by Plaintiff relating to alleged communications with governmental regulatory agencies are barred in whole or in part under applicable law, including the First and Fourteenth Amendment rights to petition the government.

#### **THIRTIETH SEPARATE DEFENSE TO ALL COUNTS**

297. Plaintiff's claims are barred in whole or in part because the commercial speech relating to Mirena<sup>®</sup> was not false or misleading and is protected under the First and Fourteenth Amendments to the United States Constitution and applicable state constitutional provisions.

#### **THIRTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

298. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate their alleged damages.

#### **THIRTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

299. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because those statutes and regulations do not contain or create any private cause of action.

#### **THIRTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

300. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of BHCP, if any, should be reduced accordingly. Pursuant to the common law right to credits, reductions and setoffs, and other applicable law, any settlement reached between Plaintiff and a named defendant in this action shall reduce the amount of Plaintiff's recovery by the stipulated amount of the agreement, or in the amount of consideration paid, whichever is greater.

#### **THIRTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

301. Plaintiff's Complaint fails to state a claim on which relief can be granted as to costs and disbursements, attorney fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, unjust enrichment, disgorgement, restitution, or treble damages.

#### **THIRTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

302. Any claim for prejudgment interest is barred by Plaintiff's failure to make a demand for payment or offer of settlement in writing, failure to send the demand or offer by certified mail, and failure to leave the demand or offer open for ninety days under RSMo § 408.040.2 and other applicable law.

#### **THIRTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

303. Plaintiff's Complaint fails to state a claim against BHCP on which relief can be granted for punitive or exemplary damages.

#### **THIRTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

304. BHCP denies any conduct for which punitive or exemplary damages could or should be awarded and denies that Plaintiff has produced evidence sufficient to support or sustain the imposition of punitive damages against BHCP pursuant to the applicable standards of proof.

#### **THIRTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

305. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad, would violate BHCP's constitutional rights as secured by the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution, and would contravene the prohibition of excessive fines and other provisions of the United States Constitution, the Missouri Constitution, and any other applicable state constitution.

**THIRTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

306. Plaintiff cannot recover punitive or exemplary damages against BHCP because such an award, which is penal in nature, would violate BHCP's rights under the United States Constitution, the Missouri Constitution, and any applicable state constitution, unless BHCP is afforded the same procedural safeguards as are criminal defendants.

**FORTIETH SEPARATE DEFENSE TO ALL COUNTS**

307. Any imposition of punitive or exemplary damages in this case against BHCP would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute an undue and unreasonable burden on interstate commerce.

**FORTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

308. With respect to Plaintiff's demand for punitive or exemplary damages, BHCP incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under Missouri law or other applicable state law.

**FORTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

309. No act or omission of BHCP was intentional, fraudulent, malicious, reckless, in any way morally culpable, or made with conscious, malicious, or intentional disregard for the health and well-being of Plaintiff or others. BHCP asserts all statutory or judicial protections from punitive or exemplary damages that are available under applicable law, and any award of punitive or exemplary damages is barred.

**FORTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

310. Plaintiff's claim for punitive damages against BHCP cannot be sustained because, in all respects pertinent to this action, BHCP complied with applicable industry standards and did not engage in a deliberate course of conduct which knowingly endangered those using Mirena<sup>®</sup>.

**FORTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

311. Plaintiff's claim for punitive damages against BHCP cannot be sustained to the extent that, prior to the entry of any judgment or award in this case, an award of punitive or exemplary damages has been recovered from BHCP in a court of this state relating to Mirena<sup>®</sup>.

**FORTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

312. Plaintiff's Complaint seeks damages in excess of those permitted by law. BHCP asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

**FORTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

313. Plaintiff's claims of injury and claims for damages are speculative.

**FORTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

314. Plaintiff's Complaint fails to state a claim on which relief can be granted for joint and several liability.

**FORTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

315. BHCP preserves all defenses relating to personal jurisdiction and venue.

**FORTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

316. BHCP adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with BHCP's defenses pleaded in this Answer.

**FIFTIETH SEPARATE DEFENSE TO ALL COUNTS**

317. BHCP has disclaimed any alleged express or implied warranties.

**FIFTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

318. BHCP reserves the right to move to bifurcate those punitive damage issues provided for by applicable law.

**FIFTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

319. To the extent that any party or non-party is found to have fault for Plaintiff's alleged injuries, Plaintiff's damages should be apportioned in accordance with the comparative fault of all parties at fault.

**FIFTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

320. Plaintiff's claims of product defect, if any, are or may be barred by Section 4 of the Restatement (Third) of Torts: Products Liability, because Mirena<sup>®</sup> complied with applicable product safety statutes and administrative regulations.

**FIFTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

321. Plaintiff's claims are barred by Sections 6(c) and (d) of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Mirena<sup>®</sup> would have prescribed and did prescribe the drug for classes of patients. In addition, reasonable instructions or warnings were provided to prescribing physicians.

**FIFTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

322. Plaintiff's claims are preempted, in whole or in part, by reason of the FDA's preamble to the *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006).

#### **FIFTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

323. Plaintiff's claims are barred because the benefits of Mirena<sup>®</sup> outweigh the risks, if any, that might be associated with the product.

#### **FIFTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

324. Plaintiff's alleged injuries and damages, if any, were the result of an idiosyncratic or allergic reaction, which BHCP could not reasonably foresee and over which BHCP had and has no control.

#### **FIFTY-EIGHTH SEPARATE DEFENSE TO ALL COUNTS**

325. Any award of punitive or exemplary damages against BHCP is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003).

#### **FIFTY-NINTH SEPARATE DEFENSE TO ALL COUNTS**

326. Whatever damages may have been sustained at the time and place alleged in Plaintiff's Complaint was caused, in whole or in part, by the culpable conduct of Plaintiff and without any negligence on the part of BHCP. Damages, if any, are to be diminished proportionally to the culpable conduct of Plaintiff.

#### **SIXTIETH SEPARATE DEFENSE TO ALL COUNTS**

327. Plaintiff's claims may be barred, in whole or in part, by the doctrines of merger, bar, *res judicata*, collateral estoppels, release, discharge, and accord and satisfaction.

#### **SIXTY-FIRST SEPARATE DEFENSE TO ALL COUNTS**

328. BHCP gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, BHCP intends to rely upon same in defense



of this action.

**SIXTY-SECOND SEPARATE DEFENSE TO ALL COUNTS**

329. BHCP denies, to the extent the actions alleged may have occurred, that any other entity engaging in the activities alleged was acting as the agent or servant of BHCP, or at the instruction or subject to the control of BHCP with regard to any of the actions described in the Complaint; thus, BHCP is not liable for any acts or omissions of such third parties as a matter of law.

**SIXTY-THIRD SEPARATE DEFENSE TO ALL COUNTS**

330. Plaintiff's claims are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Mirena<sup>®</sup> or because Plaintiff knew of the alleged risks of Mirena<sup>®</sup>.

**SIXTY-FOURTH SEPARATE DEFENSE TO ALL COUNTS**

331. Plaintiff's causes of action are barred, in whole or in part, by the failure to assert a reasonable alternative safer design for Mirena<sup>®</sup>.

**SIXTY-FIFTH SEPARATE DEFENSE TO ALL COUNTS**

332. Plaintiff's alleged reliance, if any, on alleged misrepresentations, omissions or concealment by BHCP, which is categorically denied, was not reasonable and did not cause any of the damages alleged by Plaintiff.

**SIXTY-SIXTH SEPARATE DEFENSE TO ALL COUNTS**

333. Plaintiff's causes of action for products liability are barred because the relevant product was consistent with or exceeded consumer expectations.

**SIXTY-SEVENTH SEPARATE DEFENSE TO ALL COUNTS**

334. BHCP reserves the right to amend its answer and separate and affirmative defenses

to conform to such facts as may be revealed in discovery or otherwise.

**DEMAND FOR JURY TRIAL**

335. BHCP specifically requests and demands a trial by jury on all facts and issues in this action, made up of the maximum allowable number of jurors.

**WHEREFORE**, Bayer HealthCare Pharmaceuticals Inc. denies any and all liability with regard to Plaintiff's claims, and respectfully requests that Plaintiff's claims against it be dismissed with prejudice and that Bayer HealthCare Pharmaceuticals Inc. be awarded such general, further relief as justice may require.

Dated: March 16, 2015.

Respectfully submitted,

By: /s/ Jennifer M. Stevenson  
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*Attorney for Defendant Bayer HealthCare  
Pharmaceuticals Inc.*

### **CERTIFICATE OF SERVICE**

I hereby certify that on the 16th day of March 2015, a copy of Defendant Bayer HealthCare Pharmaceuticals Inc.'s Original Answer was electronically filed with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants.

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